

paragraph and §103. For the reasons which are set forth in detail hereinbelow, Applicants respectfully submit that the amended claims presented in the instant paper address the Examiner's concerns and are thus in condition for allowance.

The §112, Second Paragraph Rejection

The Examiner has rejected claims 8 and 25 under 35 U.S.C. §112, second paragraph as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, the Examiner has questioned the use in claims 8 and 25 of term "storage stability" in these claims. Applicants respectfully traverse the Examiner's rejection.

Applicant respectfully submits that the use of the term "storage stability" in claims 8 and 25 is fully defined and as such renders claims 8 and 25 unambiguous and in compliance with the requirements of 35 U.S.C. §112, second paragraph. The attention of the Examiner to the definition of the term "storage stability" in the specification at page 9 (last line) and the first paragraph of page 10. That description of the present invention sets forth that compositions according to the present invention are storage stable as single phase emulsions at a temperature of at least 50°C for a period of at least about three months, and often longer than six months, a year or longer. Despite the clear presentation of the above-referenced definition in the present specification on pages 9-10, if the Examiner believes that inserting such language in independent claims 8 and 25 would materially advance the prosecution of this application, Applicants would agree to such limitation as supported by the specification being placed in those claims.

Applicants respectfully submit that claims 8 and 25 are presented in conformity with the requirements of §112, second paragraph.

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The §103 Rejection

The Examiner has rejected claims 1-36 as being patentable over Fogel, U.S. patent number 6,126,949 ("Fogel"), Herstein, U.S. patent number 5,902,591 ("Herstein") and McCutcheon's Emulsifiers & Detergents North American Edition, 2000, page 18 ("McCutcheon").

The Examiner cites Fogel for teaching component A, a dialkyl fumarate, especially dibehenyl fumarate to be useful to harden or stiffen an oil-in-water or water-in-oil emulsion and to enhance stability of water-in-oil emulsions. Fogel also is cited for teaching emollients to be used with dibehyl fumarate as petrolatum, mineral oil, various vegetable oils and neopentanoates such as octyl dodecyl neopentanoate and that the water-in-oil emulsion may contain varying amounts of water. Fogel is cited for also teaching the use of nonionic emulsifiers in water-in-oil emulsions.

Herstein is cited for teaching that a 5-10% vitamin C containing topical cosmetic composition employing several preferred emulsifiers, one of which is stearic monoethanolamide (component C). McCutcheon is cited generically for teaching the use of Arlacel P135 in cosmetics.

The Examiner readily admits that the references do not expressly teaching that the three components as claimed can be incorporated into a single composition. The Examiner also readily admits that the three references do not expressly teach the three components within the claimed weight ratios. Nonetheless, the Examiner argues that it would have been obvious to incorporate the three components into a single composition as an emulsion within the claimed weight ratio. Applicant respectfully strongly disagrees.

The present invention is directed to the unexpected discovery that the inclusion of a three

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component mixture of dialkylfumarate, polyethyleneglycol dihydroxystearate and alkyl monoethanolamide within the claimed weight ratios, when incorporated into an emulsion will provide an unexpected enhancement in the stability of the resulting emulsion. The present invention is directed to compositions which may be used to manufacture emulsions (claims 1-7), and emulsion compositions (claims 8-24) and personal care compositions (claims 25-36) which exhibit unexpected storage stability, each of which contains the three component mixture (A, B and C) within the claimed ratios. Contrary to the Examiner's contention, the cited prior art in no way discloses or suggests the present invention. Note that the emulsion compositions contain substantial amounts of water, which, in combination with other lipophilic components of the present invention, would normally *readily separate* into more than one phase. Applicant, with his invention, has discovered a means to maintain the emulsion as a stable single phase, as a storage stable composition. The present invention is clearly *not taught or suggested by the cited prior art*.

Fogel, as indicated by the Examiner, is directed to novel dialkyl fumarate compositions, which are cited for their use in dermatological products. The Examiner readily admits that Fogel does not disclose or suggest components B or C, which must be added to compositions according to the present invention *within the claimed weight ratios* in order to secure the unexpected characteristics of emulsion compositions (i.e., maintaining storage stability in a composition which, because of the components included, would normally readily separate into two or more phases). Although Fogel is a generally useful reference, it cannot be raised to the level of suggesting that it teaches either component B or component C of the present invention *in combination, or the weight ratios of the instant invention as set forth by the claims* for the purpose of increasing the storage stability of water-containing emulsions. Nor do the other references cited by the Examiner somehow add to Fogel to render the present invention unpatentable.

Herstein is directed to stable topical cosmetic pharmaceutical emulsions of ascorbic acid

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which comprise ascorbic acid, in combination with an emulsion composition containing a stabilizing effective amount of an organoclay composition. The Herstein compositions include anywhere from about 1% to about 10% by weight of the emulsifier. Of the literally thousands of disclosed emulsifiers which may be used in Herstein, one is stearic monoethanolamide. Notwithstanding the disclosure of this emulsifier, Herstein teaches that the emulsifier, in order to be effective *must be formulated in combination with an organoclay composition*. *Note that the reason Herstein combines the emulsifier with the organoclay composition is to avoid having the emulsion break down- that is, the organoclay composition functions as a stabilizer for the Herstein disclosed emulsion. See Herstein at column 2, lines 34-62.* Thus, Herstein provides a solution to emulsifier breakdown- by using an organoclay composition in an emulsion. In the present invention, Applicant has discovered that the combination of the three components in the claimed weight ratios is the solution to the problem Herstein solved in a totally different way.

It is posited that Herstein does not disclose or even *obliquely* suggest the use of dialkyl fumarates or polyethyleneglycol dihydroxystearate or the weight ratio which is used in the present compositions *because Herstein solved the problem of emulsifier breakdown by adding an effective amount of an organoclay composition*. This is not the present invention and does not bring to mind the present invention. The dialkyl fumarates of the present invention are not the hydrophilic gelling agents which Herstein suggests can be used to stabilize emulsions. Herstein at column 2, lines 34-62. Indeed, if anything dialkyl fumarate tends to be hydrophobic, relative to hydrophilic gelling agents. The dialkyl fumarates of Fogel are not just different animals than the hydrophilic gelling agents of Herstein, they are chemical opposites (from a physicochemical characteristic perspective). The present invention is particularly inventive in solving the same problem as Herstein by using components which are not even mentioned by Herstein. The components of the present invention are not even related physicochemically to the organoclays or other hydrophilic gelling agents of Herstein. It is respectfully submitted that Herstein adds nothing to the disclosure of Fogel which would somehow suggest to one of ordinary skill the

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invention of the present application.

Nor does the disclosure of McCutcheon somehow add to the deficient disclosures of Fogel and Herstein in failing to teach the present invention to one of ordinary skill in the art. McCutcheon is a generic reference which discloses that Arlacel 135 is a polymeric surfactant. Noted here is the fact that McCutcheon simply provides a list of emulsifiers which are commonly available. McCutcheon does not disclose or suggest the present invention. Indeed, McCutcheon does not even disclose that Arlacel 135 is PEG 1500 dihydroxystearate. Rather, McCutcheon simply refers to Arlacel 135 as a polymeric emulsifier available from ICI. It is respectfully submitted that McCutcheon is barely even relevant to the present invention and only in the sense that it provides a manufacturer for Arlacel 135 and indicates that Arlacel 135 may be used in skin care cosmetics and color cosmetics. Other than that meager disclosure, McCutcheon says nothing else about Arlacel 135.

It is respectfully submitted that the Examiner has not made out a cogent case that the present invention is obvious over the combined disclosures of Fogel, Herstein and McCutcheon. Instead, the Examiner's rejection simply cobbles together unrelated disclosures in the art which happen to be relevant to the present invention *only because of the existence of the present invention*. It is respectfully submitted that the Examiner's rejection is a classic case of *impermissible hindsight reconstruction*, the likes of which can only be made as a consequence of knowing of the present invention. It is further submitted that the Examiner's rejection is inappropriate.

Applicant respectfully submits that without the information provided in the present specification and the disclosure of the instant invention, one of ordinary skill could not possibly even combine these three isolated references, each of which refer to only a single component as claimed. Thus, Fogel may refer to dialkyl fumarate, but in no way discloses either polyethylene glycol dihydroxystearate or the alkyl monoethanolamide emulsifier. Herstein may disclose

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stearic monoethanolamide as one of numerous emulsifiers to produce stable emulsions, ***but only in combination with an organoclay compound or other hydrophilic gelling agent***. Herstein does not disclose alkyl fumarate or polyethyleneglycol dihydroxystearate emulsifiers and indeed, if anything, suggests that the present invention won't work because the present invention does not utilize a hydrophilic gelling agent. In this sense, Herstein actually *teaches away* from the present invention. McCutcheon only refers to the manufacturer of PEG 1500 dihydroxystearate, but does not provide any additional useful information. It is therefore fair to say that one of ordinary skill could not have combined the teachings of the three references when there is not even a suggestion that it is desirable to combine these components. Moreover, when taken with the fact that the present invention requires certain weight ratios of these three components in order to provide the claimed invention, it is simply not cogent that the claimed invention is obvious over a combination of the cited references.

The Examiner has posited the obviousness rejection as being that of a *prima facie* obviousness objection. It is not. A *prima facie* obviousness rejection is one that is made based upon the clear suggestion from the references which are cited to combine the components which are claimed. It is respectfully submitted that the Examiner's *prima facie* obvious rejection is not even possible, given that Herstein suggests that stable emulsions can only be made by including a hydrophilic gelling agent in the composition. See Herstein, column 1, lines 34-62. In this sense, Herstein actually *teaches away* from the present invention.

Moreover, in the present case, the specific cited references cited do not make any reference whatsoever to any of the other components used in the present invention and there is absolutely no disclosure in those references of the weight ratios of the components used in the present invention. Even the Examiner readily admits this in the office action. Thus, the Examiner's argument that the present invention is *prima facie* obvious fails on two counts. Yet, despite the absence of any teaching, as readily admitted by the Examiner, the Examiner maintains that the invention is *prima facie* obvious. It is respectfully submitted that the Examiner has not

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even made out a case that the present invention is obvious, let alone *prima facie* obvious. The Examiner is respectfully requested to withdraw this rejection as the present invention is clearly patentable.

Because the combination of references do not make out a cogent *prima facie* obviousness rejection and because a combination of references which includes the teachings of Herstein, requires that one of ordinary skill look to hydrophilic gelling agents to provide stability to emulsions, Applicant respectfully submits that the Examiner has not made out a case that the present invention is obvious over the combined teachings of Fogel, Herstein and McCutcheon.

It is respectfully submitted that Applicant has effectively addressed the Examiner's rejection of the originally filed claims under §§112 and 103, and the rejections are respectfully requested to be withdrawn.

For all of the above reasons, Applicant respectfully asserts that the claims set forth in the amendment to the application of the present invention are now in compliance with 35 U.S.C. Applicants respectfully submit that the present application is now in condition for allowance and indication of such allowability is earnestly solicited.

Applicants have neither cancelled nor added any claim. No fee is therefore due for the presentation of this amendment. A notice of appeal is enclosed.

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The Commissioner is authorized to charge the notice of appeal fee of \$160 to deposit account 04-0838. If any additional fee is due or any overpayment has been authorized please charge/credit Deposit Account No. 04-0838.

Respectfully submitted,

June 16, 2003

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Certificate of Facsimile Transmission

I hereby certify that this correspondence is being sent by facsimile transmission to Examiner S.U. Hui in Group Art Unit 1617 of the United States patent and trademark Office, P.O. Box 1450, Alexandria, Virginia 22313-1450 on June 17, 2003.


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